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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/765,111 | 01/18/2001 | Jonathan A. Fletcher | B0801/7196 ERP/MAT | 8258 |

7590 06/20/2002

Elizabeth R. Plumer
c/o Wolf, Greenfield & Sacks, P.C.
Federal Reserve Plaza
600 Atlantic Avenue
Boston, MA 02210-2211

[REDACTED] EXAMINER

PRIEBE, SCOTT DAVID

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1632

DATE MAILED: 06/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|--------------------------------------|----------------------------------------|
| Office Action Summary | Application No. 09/765,111 | Applicant(s) FLETCHER ET AL. |
| | Examiner Scott Priebe | Art Unit 1632 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-5,7,9,10,15-17,21,27,28,33,41,47,53 and 58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-5,7,9,10,15-17,21,27,28,33,41,47,53 and 58 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.

- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

Art Unit: 1632

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5, 7, 9, 10 and 21, drawn to polynucleotides of SEQ ID NO: 1 (including SEQ ID NO: 7), classified in class 536, subclass 23.5.
- II. Claims 1-5, 7, 9, 10 and 21, drawn to polynucleotides of SEQ ID NO: 3 (including SEQ ID NO: 9), classified in class 536, subclass 23.5.
- III. Claims 1-5, 7, 9, 10 and 21, drawn to polynucleotides of SEQ ID NO: 5 (including SEQ ID NO: 11), classified in class 536, subclass 23.5.
- IV. Claims 1-5, 7, 9, 10 and 21, drawn to polynucleotides of SEQ ID NO: 22, classified in class 536, subclass 23.5.
- V. Claims 15-17, drawn to polypeptides of SEQ ID NO: 2, classified in class 530, subclass 358.
- VI. Claims 15-17, drawn to polypeptides of SEQ ID NO: 4, classified in class 530, subclass 358.
- VII. Claims 15-17, drawn to polypeptides of SEQ ID NO: 6, classified in class 530, subclass 358.
- VIII. Claims 15-17, drawn to polypeptides of SEQ ID NO: 23, classified in class 530, subclass 358.

Art Unit: 1632

- IX. Claims 24, 27 and 28, drawn to a compound which binds a PAX8-PPAR γ 1 polynucleotide, classified in class 536, subclass 388.21.
- X. Claims 24, 27 and 28, drawn to a compound which binds a PAX8-PPAR γ 1, classified in class 530, subclass 387.7.
- XI. Claim 33, drawn to a method for detecting a PAX8-PPAR γ 1 polynucleotide, classified in class 435, subclass 6.
- XII. Claims 33 and 47, drawn to a method for detecting a PAX8-PPAR γ 1 polypeptide, classified in class 435, subclass 7.1.
- XIII. Claim 41, drawn to a method of treatment with a PPAR γ 1 ligand, classified in class 514, subclass 369.
- XIV. Claim 53, drawn to a screen for agents that inhibit production of PAX8-PPAR γ 1 polypeptide, classified in class 435, subclass 29.
- XV. Claim 58, drawn to treatment with an agent that interferes with function of a PAX8-PPAR γ 1 polynucleotide, e.g. antisense nucleic acid, classified in class 514, subclass 44.
- XVI. Claim 58, drawn to an agent that interferes with function of a PAX8-PPAR γ 1 polypeptide other than a PPAR γ 1 ligand, cannot be classified no agents disclosed.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 86.05 for inventive groups that are directed to different products, restriction is deemed to

Art Unit: 1632

be proper because these products appear to constitute patentably distinct inventions for the following reasons. The polynucleotides of inventions I-IV are structurally different polynucleotides which encode structurally different polypeptides, and are not obvious one over the other. The polypeptides of inventions V-VIII are structurally different polypeptides not obvious one over the other. The polynucleotides of inventions I-IV are structurally and functionally different compounds, than the polypeptides of inventions V-VIII, and have different uses. The binding agents of inventions IX and X are structurally and functionally different compounds than the polynucleotides of inventions I-IV and polypeptides of inventions V-VIII, respectively. The compounds of invention IX do not bind to the polypeptides of inventions V-VIII, and the compounds of invention X do not bind to the polynucleotides of inventions I-IV.

The polynucleotides of inventions I-IV are not used in the methods of inventions XII-XIV and XVI, and are therefore unrelated to these methods. The polypeptides of inventions V-VIII are not used in the methods of inventions XI-XVI, and are therefore unrelated to these methods. The compounds of invention IX are not used in the methods of inventions XII, XIII, and XVI, and are therefore unrelated to these methods. The compounds of invention X are not used in the methods of inventions XI, XIV and XV, and are therefore unrelated to these methods.

Inventions I-IV and inventions XI and XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

Art Unit: 1632

product (MPEP § 806.05(h)). In the instant case invention XI can be practiced with antibodies that bind the polynucleotides of inventions I-IV, and invention XV can be practiced with agents that inhibit production of a PAX8-PPAR γ 1 mRNA (rather than to cause destruction of the mRNA).

Invention IX and inventions XI, XIV and XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compounds of invention IX can be used in any of the methods of inventions XI, XIV and XV, and inventions XIV and XV can be practiced with compounds that do not bind polynucleotides, e.g. agents which inhibit production of a PAX8-PPAR γ 1 mRNA (rather than to cause destruction of the mRNA).

Inventions X and inventions XII, XIII, and XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compounds of invention X can be used in any of the methods of inventions XII, XIII and XVI or for affinity purification of a polypeptide of inventions V-VIII.

Art Unit: 1632

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for each invention is not required for the other inventions, and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Certain papers related to this application may be submitted to Art Unit 1632 by facsimile transmission. The FAX numbers are (703) 308-4242 or (703) 305-3014 for any type of communication. In addition, FAX numbers for a computer server system using RightFAX are also available for communications before final rejection, (703) 872-9306, and for communications after final rejection, (703) 872-9307, which will generate a return receipt. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (703) 308-7310. The examiner can normally be reached on Monday through Friday from 8 AM to 4 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

Any inquiry concerning administrative, procedural or formal matters relating to this application should be directed to Patent Analyst Patsy Zimmerman whose telephone number is

Application/Control Number: 09/765,111

Page 7

Art Unit: 1632

(703) 308-8338. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Scott D. Priebe, Ph.D.
Primary Examiner
Technology Center 1600
Art Unit 1632